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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/804,571	03/19/2004	Francis L. Garing	DEKA:319US	7085

32425 7590 09/21/2006

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EXAMINER	
KALLIS, RUSSELL	
ART UNIT	**PAPER NUMBER**
1638	

DATE MAILED: 09/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/804,571	GARING, FRANCIS L.	
	Examiner	Art Unit	
	Russell Kallis	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 September 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *9/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-26 are pending and examined.

Claims 1, 5, 14, 15, 16, 19, 20 and 25 are objected to for the inclusion of a blank line where the ATCC Accession number should be.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 5, 15, 19-20 and 25 and claims 2-4, 6-14, 16-18, 21-24 and 26 dependent thereon, are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 6, 19 and 20, and claims 2-5, 7-18, 21-22 and 23 dependent thereon, are indefinite in the recitation of "corn variety I116412", given that a name does not clearly identify the claimed corn variety and seed, and does not set forth the metes and bounds of the claimed invention. Since the name I116412 is not known in the art, the use of said name does not carry art recognized limitations as to the specific characteristics or essential characteristics which are associated with that denomination. In addition, the name appears to be arbitrary and the specific characteristics associated therewith could be modified, as there is no written description of the corn plant that encompasses all of its traits. Amending the claims to recite the ATCC deposit number would overcome the rejection.

Claims 3 and 4 fail to further limit the deposited variety recited in claims 1 and 2. The population recited in Claim 2 is that of a deposited line of Claim 1 wherein the line is homogeneous or inbred. Further definitions in Claims 3 and 4 reciting "essentially

homogeneous" and "essentially free from hybrid seed" are contrary to the definition of the deposited line.

Claim 14 is indefinite because the claim fails to recite required claim elements. The recitation of "capable of" suggests and/or indicates that the physiological and morphological characteristics of the deposited line are not expressed. Deletion of "capable of" from the claim would obviate this rejection.

Claim 21 recites "a corn genome" that lacks antecedent basis. The deposited line recited in independent claim 20 from which claim 21 depends, is drawn to the genome of deposited line I116412. Amending the claim to recite "said corn genome" would obviate this rejection.

Claims 1-26 are rejected under 35 USC 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Since the seed claimed is essential to the claimed invention, it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If a seed is not so obtainable or available, the requirements of 35 U.S.C. 112 may be satisfied by a deposit thereof. The specification does not disclose a repeatable process to obtain the exact same seed in each occurrence and it is not apparent if such a seed is readily available to the public. It is noted that applicants intend to deposit seeds for I116412 at the ATCC, but there is no indication that the seeds have been deposited and there is no indication in the specification as to public availability. If the deposit of these seeds is made under the terms of the Budapest Treaty, then an affidavit or declaration by the applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the seeds will be irrevocably and without restriction or condition released to the public upon the issuance of a patent would satisfy the

deposit requirement made herein. A minimum deposit of 2500 seeds is considered sufficient in the ordinary case to assure availability through the period for which a deposit must by maintained.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit, meets the criteria set forth in 37 CFR 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number showing that

(a) during the pendency of the application, access to the invention will be afforded to the Commisioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the enforceable life of the patent, whichever is longer; (d) the viability of the biological material at the time of deposit will be tested (see 37 CFR 1.807); and

(e) the deposit will be replaced if it should ever become inviable.

Claims 20-24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of introducing a desired trait into corn variety I116412 by backcrossing the progeny plants three or more times to produce fourth or higher progeny plants to retrieve essentially all the alleles found at the same loci of corn variety I116412 and the desired trait, does not reasonably provide enablement for backcrossing the progeny plants one or two times to retrieve all essentially all the alleles found at the same loci of corn variety I116412

and the desired trait. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claimed invention is not supported by an enabling disclosure taking into account the *Wands* factors. *In re Wands,* 858/F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). *In re Wands* lists a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and/or use the invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claim.

The claims are broadly drawn to a method of introducing a single gene trait into corn variety I116412 using an unknown parent in a recurrent backcross to corn variety I116412 and plants comprising desired traits produced thereby.

Applicant teaches corn variety I116412 and describes a method of backcrossing using an unknown parent.

Applicant does not teach a corn plant having all the alleles found at the same loci of corn variety I116412 and a desired trait by backcrossing only once or twice to an unknown parent.

The state-of-the-art does not recognize a method of backcrossing only once, twice or thrice to a recurrent parent that would retrieve a first, second or third backcross progeny plant that has all the alleles found at the same loci of corn variety I116412 and the desired trait. The procedure for a backcross that would transfer a desired trait and retrieve all the characteristics of

the recurrent parent would require at least 4 backcrossing steps (i.e. repeating steps 'c' and 'd' in claim 20 for at least three additional backcrosses) to get a progeny plant that has all the alleles found at the same loci of corn variety I116412; and is described in Poehlman J.M. and Sleper D.A, Breeding Field Crops, 4th ed. (1995), Iowa State University Press; on pages 172 to 174; see figure 9.6. Clearly, as figure 9.6 points out a first, second or third backcross progeny plant would not retrieve all or essentially all the alleles found at the same loci of corn variety I116412, but rather would require at least several additional backcrosses. Further, the authors also suggest that the method is most easily carried out when the trait to be transferred is simply inherited or single gene (i.e. a simple locus) and dominant and easily recognized; and thus the recitation of yield enhancement, improved nutritional quality and yield stability in claim 23 is not supported by any method taught in the specification or in the art.

Given the lack of guidance in the instant specification, undue trial and error experimentation would be required for one of ordinary skill in the art to screen a multitude of progeny plants to find any if at all that have all the alleles found at the same loci of corn variety I116412 and the desired trait after only one, two or three backcrosses.

Therefore, given the breadth of the claims; the lack of guidance and working examples; the unpredictability in the art; and the state-of-the-art as discussed above, undue experimentation would be required to practice the claimed invention, and therefore the invention is not enabled throughout the broad scope of the claims.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Kallis whose telephone number is (571) 272-0798. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Russell Kallis Ph.D.
September 14, 2006

RUSSELL P. KALLIS, PH.D.
PRIMARY EXAMINER